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Journal

ISSN

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Publication Date

DOI

Peer reviewed

Defining High Risk: Cost-effectiveness of Extended Duration Thromboprophylaxis Following Major Oncologic Abdominal Surgery

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Abstract

Purpose—Extended duration thromboprophylaxis (EDTPPX) is the practice of prescribing antithrombotic therapy for 21 days after discharge, commonly used in surgical patients who are at high risk for venothromboembolism (VTE). While guidelines recommend EDTPPX, criteria are vague due to a paucity of data. The criteria can be further informed by cost-effectiveness thresholds. This study sought to determine the VTE incidence threshold for the cost-effectiveness EDTPPX compared to inpatient prophylaxis.

Methods—A decision tree was used to compare EDTPPX for 21 days after discharge to 7-days of inpatient-prophylaxis with base case assumptions based on an abdominal oncologic resection without complications in an otherwise healthy individual. Willingness to pay was set at $50,000/QALY. Sensitivity analyses were performed to assess uncertainty within the model, with particular interest in the threshold for costeffectiveness based on VTE incidence.

Results—EDTPPX was the dominant strategy when VTE probability exceeds 2.39%. Given a willingness to pay threshold of $50,000/QALY, EDTPPX was the preferred strategy when VTE incidence exceeded 1.22% and 0.88% when using brand name or generic medication costs respectively.

Conclusions—EDTPPX should be recommended whenever VTE incidence exceeds 2.39%. When post-discharge estimated VTE risk is 0.88%–2.39% patient preferences about self-injections and medication costs should be considered.

Introduction

Venothromboembolism (VTE) encompassing both deep vein thrombosis (DVT) and pulmonary embolism (PE), represents a major health care burden leading the Surgeon

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General to release a call to action in 2008. Between 100,000 and 180,000 deaths in the US are attributable to VTE annually and nearly 4 million surgical patients are at elevated risk each year. [1, 2] The Agency for Healthcare Research & Quality has stated that provision of thromboprophylaxis is one of the most important steps to improve patient safety. [1] Many initiatives have focused on inpatient prophylaxis, yet increasing evidence demonstrates that VTE risk is prolonged well beyond the inpatient episode. The Million Women Study found that there was heightened VTE risk for up to 12 weeks following surgery, and nearly 40% of all surgery related VTE occur within 21 days after surgery. [3, 4]

In an attempt to address this prolonged period of risk, randomized controlled trials in major abdominal oncologic resections have demonstrated that 28 days of low molecular weight heparin (LMWH) decreases the rate of both asymptomatic and symptomatic VTE compared to inpatient prophylaxis alone.[5–7] These findings have led to national and international consensus guidelines recommending the use of extended duration thromboprophylaxis (EDTPPX) following major abdominal or pelvic resections for cancer.[8, 9]

The use of LMWH for a total of 28 days following surgery is not a simple decision as there are trade-offs that require consideration. The cost of LMWH can be a considerable financial burden to both the patient and the health care system. [10] Recognition of this burden led the American College of Chest Physicians to include a comment about discussing EDTPPX with patients with particularly attention to their financial preferences. [11] Another major trade-off for patients is the requirement for self-injections which is less preferred and has been associated with a decreased quality of life compared to oral agents. [12] The trade-offs, particularly the increased cost associated with LMWH, necessitates an analysis of the economic feasibility of EDTPPX. Given LMWH's impact on quality of life a cost-effectiveness analysis incorporating the patient perspective will help determine when EDTPPX should be applied.

This study is aimed at defining would benefit from post-discharge thromboprophylaxis. To achieve this aim this study utilizes a cost-effectiveness analysis to determine the threshold VTE incidence where extended duration thromboprophylaxis following major oncologic abdominal resections is cost-effective.

Methods

A decision analytic model was developed to compare relative costs and health outcomes of two prophylactic strategies. The base case scenario was a major abdominal surgery for cancer in a middle aged, otherwise healthy individual, with no history of prior VTE who had a 7-day inpatient stay and successfully completed inpatient thromboprophylaxis and did not have any surgical complications. Two competing strategies were included in the model: inpatient prophylaxis for the 7 day inpatient stay only or an additional 21 days of low molecular weight heparin after discharge (28 days total).

The decision tree was developed using proprietary software (TreeAge Pro 2013 Software, Wiliamstown, MA). The decision takes place at post-operative day 7 where the patient either received 21 more days of low molecular weight heparin, or received care as usual with no

further thromboprophylaxis (Figure 1). Since LMWH is administered via a subcutaneous self-injection which may be associated with poor patient compliance, patients were considered to be either compliant or non-compliant with EDTPPX. If non-compliant, the efficacy of EDTPPX was considered to drop to baseline and costs were considered to be the same as those prescribed the drug assuming thr drug had already been purchased. Compliant patients were considered to receive full benefit of prophylaxis. Bleeding risk and heparin induced thrombocytopenia were not considered in the model since in randomized controlled trials of extended duration thromboprophylaxis neither was significantly increased in the EDTPPX cohort. [5, 6]

The model included development or no development of VTE. After VTE development the event was categorized as either PE or DVT. If a PE occurred the tree incorporated a risk of progression to death. If a DVT occurred, there was a possibility of progressing to post-thrombotic syndrome (PTS). There was no additional cost for death, while there was an additional cost associated with PTS. Due to relative infrequency, simultaneous PE and DVT were not considered and progression of DVT to VTE was not included in the analysis.

Event probabilities

Base case assumptions with sensitivity ranges are reported in Table 1. Event probabilities for relative PE and DVT rates were taken from analysis of symptomatic events following colectomy for cancer using the National Surgical Quality Improvement Program database, a large nationally validated clinical database. [13] The relative reduction in VTE events with EDTPPX was derived using published meta-analysis of EDTPPX. [6] As event probability, utility, and cost were all based on symptomatic events, the estimated reduction in VTE after EDTPPX was based on the relative reduction in symptomatic events as well. Risk of VTE was considered constant across the additional 21 days of prophylaxis.

Cost

Cost was from the health care system perspective and the cost following PE, VTE and PTS were derived from PharMetrics Patient-Centric Database, comprised of fully adjudicated medical and pharmaceutical claims within the US from 2004. [14] Cost estimates were adjusted for inflation using the consumer price index for 2013 US health care dollars. LMWH became available as a generic drug in 2012 and analysis was performed using brand and subsequently generic drug prices. The inpatient regimen was considered to be the same and thus no difference in cost for the inpatient period was included. LMWH cost was modeled for 21 additional days of 40mg LMWH using data from the outpatient pharmacy at the University of Rochester Medical Center in 2013. [15] VTE related costs were modeled over 1 year and as such no discount was included. The cost of VTE development in the intervention arm incurred the full medication cost as well as the additional cost associated with the event.

Health Outcomes

Effectiveness was defined from the patient perspective using quality adjusted life years calculated using utility weights over a 1 year time horizon. No data on utility values

following abdominal oncologic surgery were available thus utility values were extrapolated from other similar major surgeries. [16, 17]

Cost Effectiveness Analysis

The preferred strategy thresholds were determined using the incremental cost effectiveness ratio calculated using the difference in cost between the two interventions per unit difference in effect. The willingness to pay threshold was set at $50,000/QALY.

Sensitivity Analysis

We used sensitivity analysis to evaluate the impact of uncertainty around baseline assumptions of the model. Ranges were based on the range of reported values, confidence intervals, or were assigned wide ranges where evidence was not available.

Results

Cost was first evaluated independently with results stratified by brand versus generic medication costs. When brand name LMWH medication costs were used, EDTPPX minimized cost when the VTE probability reached 1.2% (Figure 2). This threshold decreased when using generic LMWH costs to 0.2% (Figure 3).

The effectiveness threshold was then evaluated independently using QALY as the unit of effectiveness. The use of brand or generic LMWH did not alter effectiveness results. EDTPPX became the preferred strategy when the VTE probability reached 2.4% (Figure 4).

Cost-effectiveness as determined by the incremental cost-effectiveness ratio is reported stratified by brand vs. generic medication costs. When brand name LMWH costs were used, EDTPPX became the dominant strategy (both less costly and more effective) when VTE probability reached 2.39%. Use of generic LMWH did not alter this threshold (Table 2).

When a competing intervention is not dominant, the preferential strategy depends on the willingness to pay which was set at 50,000/QALY. At this willingness to pay level, EDTPPX with brand medication costs was the preferred strategy when VTE probability reached 0.165%. When generic medication costs were used, EDTPPX was preferred when VTE probability reached 0.88%.

Inpatient prophylaxis was the dominant strategy (both less costly and more effective) if VTE probability was less than 1.22% and 0.165% for brand and generic medication costs respectively

As shown in figure 5, the model was most sensitive to the cost of medication. The next most important variable was the probability of VTE. The model was also sensitive to the cost of a DVT and PE, the disutility associated with LMWH use, the QALY associated with PE and DVT, the relative reduction in VTE after EDTPPX, and patient compliance. When evaluating the tornado diagram for the ICER, the model was most sensitive to probability of VTE, the cost of medication, and the QALY associated with experiencing a DVT.

Discussion

Two major consensus guidelines recommend extended thromboprophylaxis following abdominal oncologic resections yet utilization remains low. EDTPPX use in general surgery is lagging as evidenced in a 2007 study of abdominal surgical cases where only 1.2% received post-discharge thromboprophylaxis. [18] Another study found that 23% of abdominal cancer cases received EDTPPX compared to 77% in corresponding orthopedic cases, demonstrating a clear gap in quality. [19] Poor guideline compliance may be due vague definitions of who might benefit from EDTPPX. The NCCN guidelines are broad using a "blanket approach" in their recommendations. They recommend VTE prophylaxis for up to four weeks post-operation for abdominal or pelvic cancer surgery patients including all gastrointestinal malignancy cases [Grade 2A]. [20] The American College of Chest Physicians 9th edition guidelines on prevention of thrombosis recommend EDTPPX for high-VTE-risk patients undergoing abdominal or pelvic surgery for cancer (not at otherwise high risk for major bleeding) [grade 1B]. [21] While all other ACCP recommendations reference stratified risk scoring systems, the recommendation regarding EDTPPX does not, in large part because no such risk score yet exists. The ambiguity of high risk in the post-discharge setting may be another contributing factor to lack of guideline compliance.

Instead of using the conceptual framework of "high risk" which at the outset is vague and referential, this study sought to define the appropriate use of EDTPPX as when it is cost-effective. EDTPPX with generic LMWH is cost-effective when VTE probability exceeds 0.88% and when brand name LMWH medication costs were used, EDTPPX was cost-effective when VTE probability exceeded 1.6%. Within the National Surgical Quality Improvement Program database after colon and rectal resections for cancer, the post-discharge symptomatic VTE rate at 30-days is 0.66%. [13] Partial and total pancreatic resections for malignancy are associated with a post-discharge VTE incidence of 0.9% at 90 days and other major abdominal resections fall within this range. [22] These incidence rates falls within the range where medication cost and patient rating of the utility of LMWH alter the cost-effectiveness of EDTPPX. Thus, for most major abdominal oncologic resections a more nuanced approach to EDTPPX use is warranted.

This study also helps inform high-risk for use in the ACCP guidelines. Regardless of whether medication was generic or brand when VTE probability exceeded 2.39% EDTPPX was the dominant strategy, and should help define when EDTPPX is warranted. When predicted VTE risk for patients is between 0.88% and 1.6%, the EDTPPX should be considered, but ultimate recommendation should rely on whether generic LMWH is available. Furthermore, when VTE risk is between 0.88% and 2.39 percent, patient opinions about the disutility of self-injections should be elicited and should help guide individualized decisions. Using a patient centered approach for these patients may be the most appropriate way to implement EDTPPX since within this range patient preferences and cost may alter whether EDTPPX is cost-effective for that patient.

This study has limitations secondary to the level of uncertainty regarding the baseline estimates. This study was not meant to determine whether EDTPPX in abdominal oncologic

resections is cost-effective at given baseline parameters, but rather determine the range of VTE for which it might be considered for use. Dominance of EDTPPX was stable to changes in medication costs within the sensitivity range suggesting that the VTE risk estimate of 2.39% for use is an appropriate estimate. There is limited data on utility weights following abdominal oncologic surgery, and thus this data was extrapolated from existing literature for other major surgeries. It is possible that patients undergoing surgery for GI malignancies weight both the surgery and subsequent complications such VTE differently. Changes in these utilities may alter ultimate results. The decision tree used in this analysis simplifies the relative complex disease course of venothromboembolism following surgery, but the model attempted to account for some of this uncertainty with a robust sensitivity analysis.

Conclusion

Extended thromboprophylaxis with LMWH is the dominant cost-effective strategy when VTE incidence exceeded 2.39% regardless of whether generic or brand name drug costs were assumed. When post-discharge VTE risk is estimated from 0.88%–2.39% patient preferences about self-injections and medication costs should be considered to provide patients with an individualized decision that maximizes the cost effectiveness for them. These findings should be used to inform future guidelines about EDTPPX use following colorectal cancer resections.

Acknowledgments

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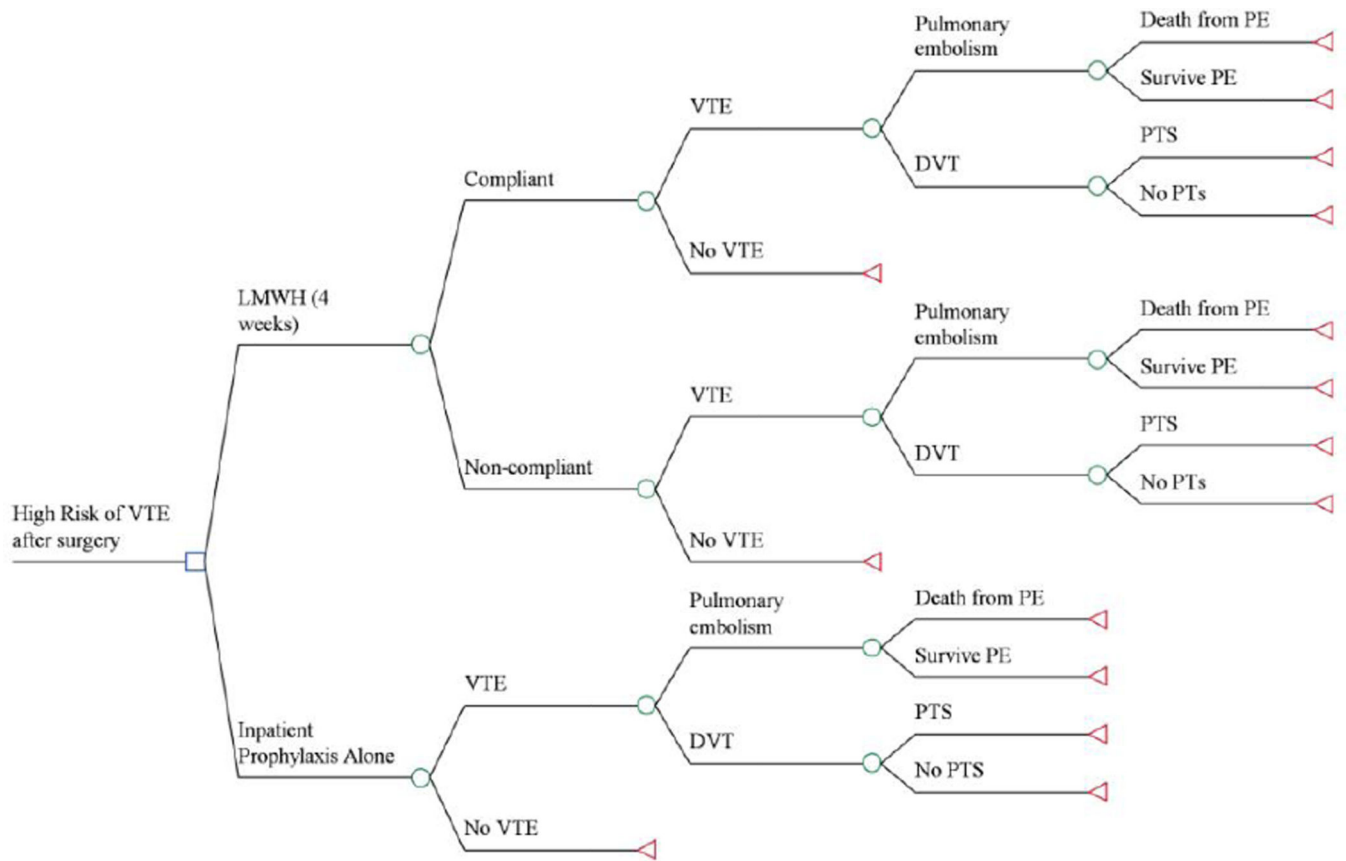
Figure 1. Decision Analysis Tree
VTE: Venothromboembolism; DVT: Deep Vein Thrombosis; EDTPPX:Extended Duration
Thromboprophylaxis; PE: Pulmonary Embolism; LMWH: Low Molecular Weight Heparin,
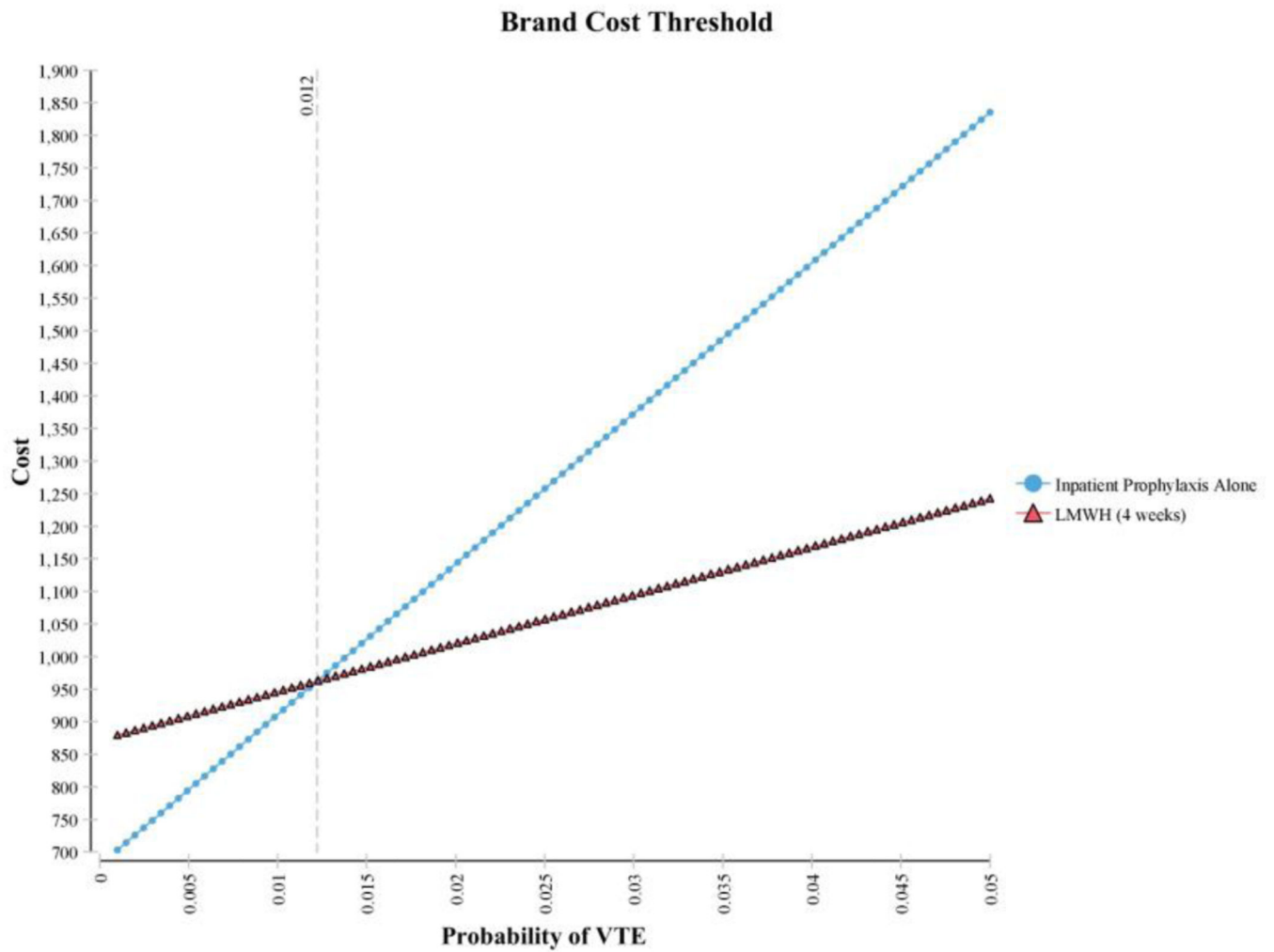PTS: Post-thrombotic Syndrome

Brand Cost Threshold

Figure 2. Cost Threshold for Brand Name LMWH
Cost minimization threshold demonstrating that if VTE probability exceeds 1.2% following discharge from the hospital, extended duration thromboprophylaxis is the preferred cost minimizing option. Cost in 2013 US dollars.
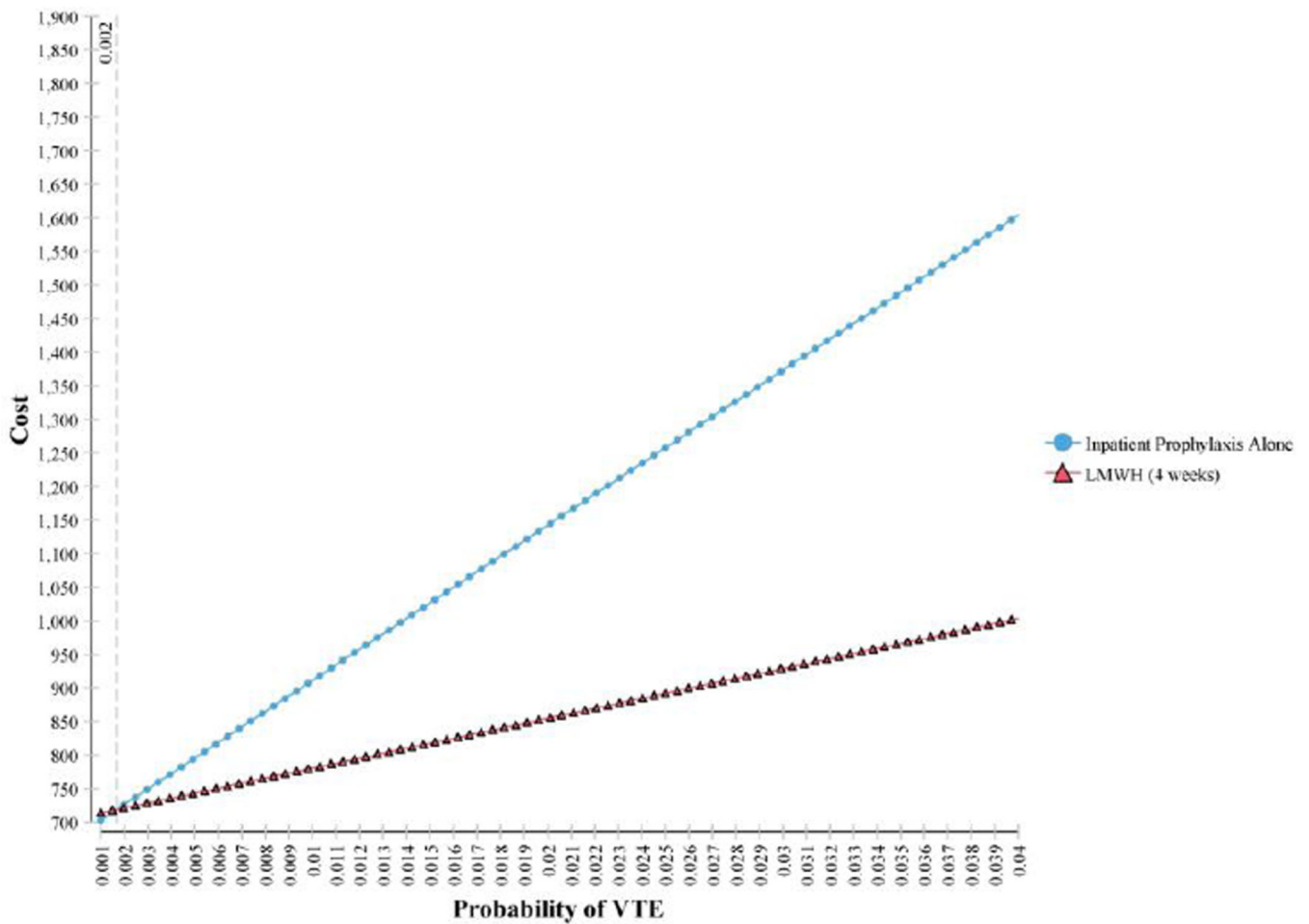
Figure 3. Cost Minimization Threshold for Generic LMWH
. Cost minimization threshold for generic LMWH demonstrating that if VTE probability exceeds 0.2% following discharge from the hospital, extended duration thromboprophylaxis is the preferred cost minimizing option.
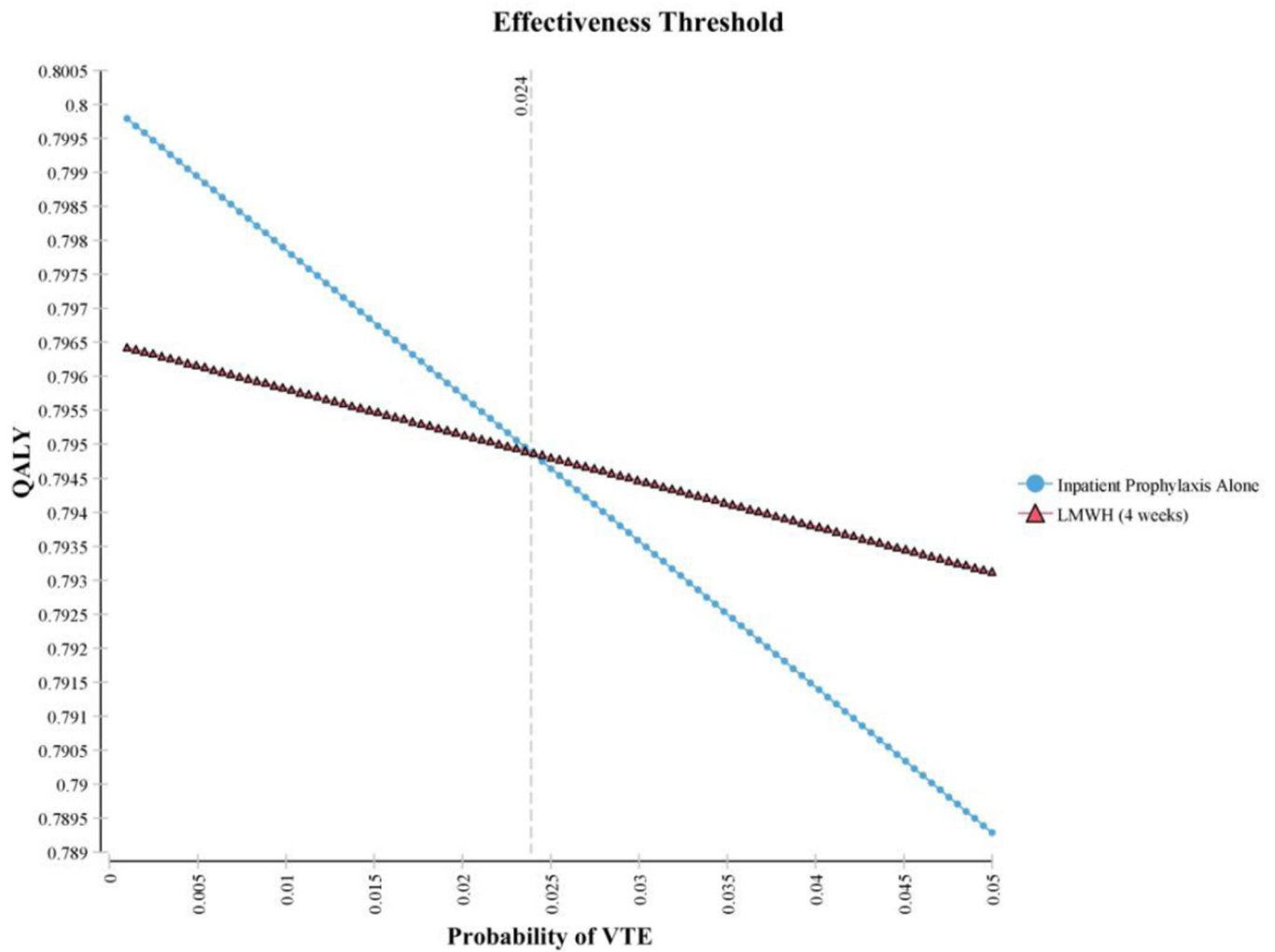
Effectiveness Threshold

Figure 4. Effectiveness Threshold for Extended Duration Thromboprophylaxis by probability of post-discharge VTE

Effectiveness threshold demonstrating that when probability of VTE exceeds 2.5% extended duration thromboprophylaxis with LMWH is the preferred strategy to maximize effectiveness.
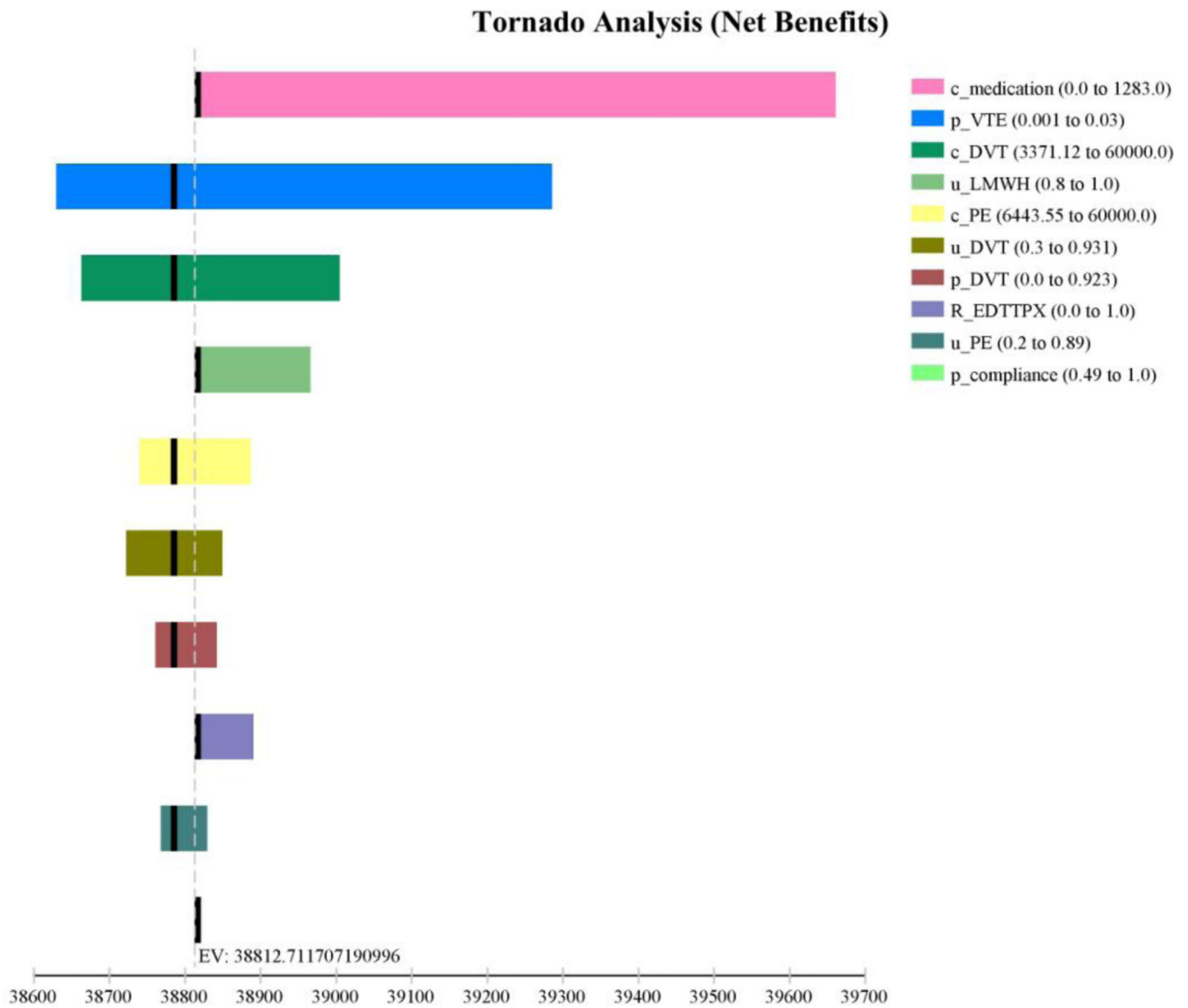
Tornado Analysis (Net Benefits)

EV: 38812.711707190996

c_medication (0.0 to 1283.0)
p_VTE (0.001 to 0.03)
c_DVT (3371.12 to 60000.0)
u_LMWH (0.8 to 1.0)
c_PE (6443.55 to 60000.0)
u_DVT (0.3 to 0.931)
p_DVT (0.0 to 0.923)
R_EDTTPX (0.0 to 1.0)
u_PE (0.2 to 0.89)
p_compliance (0.49 to 1.0)

Figure 5. Tornado Diagram
C_medication: Cost of medication; p_VTE: Probability of VTE; c_DVT: Cost of DVT;
u_LMWH: utility of low molecular weight heparin; c-PE: Cost of pulmonary embolism;
u_DVT: utility of deep vein thrombosis; p_DVT: probability of deep vein thrombosis;
R_EDTPPX: reduction in venothromboembolism with extended duration
thromboprophylaxis; u_PE: utility of PE; p_compliance: probability of compliance.

Table 1

Baseline Assumptions and Sensitivity Range

Variable	Baseline Assumption (Sensitivity Range)	Reference
Probability of Medication Compliance	0.877 (0.49–1)	[10, 23]
Probability of VTE	0.015 (0.001–0.05)	N/A
Probability of DVT if any VTE	.705 (0–0.923)	[13]
Probability of Post Thrombotic Syndrome	0.172 (0.038–0.2)	[24]
Reduction in VTE risk with EDTPPX	0.22 (0–1)	[5, 6]
Probability of Death	0.264 (0–0.264)	[25]
Cost of PE	$23248.23 (6443.55–60,000)	[14, 26]
Cost of DVT	$21539.76 (3371–60,000)	[14, 26]
Cost of Post Thrombotic Syndrome	$14362.71 (0–15,000)	[14, 26]
Cost of Generic LMWH	$705.74 (0–1283)	[15]
Cost of Brand Name LMWH	$871.74 (0–1283)	[10, 15]
Baseline Annual Medical Costs	680 (0–680)	[14]
Utility of LMWH	0.995 (0.8–1)	[12, 27]
Utility of DVT	0.84 (0.3–0.931)	[17]
Utility of PE	0.76 (0.2–0.89)	[17]
Utility of Abdominal surgery	0.8 (0–1)	[16]
Utility of Post Thrombotic Syndrome	0.754 (0–0.754)	[28]
Utility of death	0 (0)	Assumed

VTE: Venothromboembolism; DVT: Deep Vein Thrombosis; EDTPPX:Extended Duration Thromboprophylaxis; PE: Pulmonary Embolism; LMWH: Low Molecular Weight Heparin.

Table 2

Threshold Values by Medication Cost

Variable	VTE Probability	
	Brand LMWH	**Generic LMWH**
Cost Threshold	1.20%	0.20%
Effectiveness Threshold	2.40%	2.40%
Inpatient Prophylaxis Dominates	<1.22%	<0.165%
EDTPPX Dominates	>2.39%	>2.39%
WTP Threshold	1.60%	0.88%

WTP: Willingness to Pay ($50,000 per QALY) VTE: Venothromboembolism LMWH: Low Molecular Weight Heparin